

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WISCONSIN**

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PROMEGA CORPORATION,

Plaintiff,

and

MAX-PLANCK-GESELLSCHAFT zur  
FORDERUNG der WISSENSCHAFTEN E.V.,

Case No. 10-cv-281-bbc

Involuntary Plaintiff,

v.

LIFE TECHNOLOGIES CORPORATION,  
INVITROGEN IP HOLDINGS, INC., and  
APPLIED BIOSYSTEMS, LLC,

Defendants.

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**DEFENDANTS' SUPPLEMENTAL BRIEF REGARDING  
FORENSIC RESEARCH, EDUCATION, AND TRAINING**

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Defendants Life Technologies Corporation, Applied Biosystems, LLC, and Invitrogen IP Holdings, Inc., (collectively, “Life”), by and through counsel, respectfully submit this Supplemental Brief Regarding Forensic Research, Education, and Training.

### **INTRODUCTION**

On summary judgment, Life argued that “*all sales* of Defendants' AmpF $\ell$ STR kits are within the scope of a license granted by Promega under a 2006 Cross License Agreement.” (Life’s Opp., Dkt. No. 253, at 14 (emphasis added).) In response, Promega only contended that sales involving bone marrow monitoring (chimerism), genotyping hydatidiform moles, cancer analysis, cell line authentication, determination of fetal sex, and archeological and anthropological research were not with the scope of that license. (Promega’s Reply, Dkt. No. 280 at 30-37). The court noted in its order that “[t]he parties dispute whether several kinds of applications performed by the accused products sold by defendants fall within the scope of the license agreement: chimerism in the context of bone marrow transplant monitoring, cell line authentication, classifying molar specimens and determination of fetal sex. (Nov. 29, 2011 Op. and Order, Dkt. No. 345, at 23.) In light of Life’s assertion that all of its sales were covered by the license, and the Court’s recognition that Promega only contested certain specific applications, under this Court’s application of waiver, Promega has waived its argument that any other uses are not covered by the license. (See Feb. 1 Op. and Order, Dkt. No. 486, at 7.)

The Court has requested further briefing what the parties consider to be the definition of forensic research, education, and training and, presumably, how those activities relate to the licensed fields under the cross license.

## **DISCUSSION**

The 2006 Cross License applies to "Forensics and Human Identity Applications" and paternity applications. "Forensics and Human Identity Applications" includes STR testing for "use in, or in preparation for, legal proceedings" and "analysis of biological specimens for identification of individuals." It is undisputed that forensic casework and databasing (building the data base of DNA profiles against which a case sample is compared) are within the scope of the license. The question for which the Court requested supplemental briefing, is whether the license language includes use of STR kits for forensic research, forensic education, and forensic training.

Forensic research is not a precise term, but would include developmental validation (including population studies) and internal validation. Forensic education involves academic instruction leading to a degree in forensic science or a specialty thereof. Forensic training involves training in forensic labs to establish and maintain qualifications and competency in forensic testing.

As discussed below, forensic research, forensic education, and forensic training are integrally related to, and prerequisites for, the generation and admission of forensic analyses based upon STR testing in legal proceedings. Moreover, such activities are done in "preparation for" legal proceedings and, as such, any interpretation of "Forensics and Human Identity Applications" necessarily must also include forensic research, forensic education, and forensic training.

Life respectfully notes that under California law, which governs the interpretation of the Cross License,<sup>1</sup> it is appropriate and necessary for this Court to consider extrinsic evidence to

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<sup>1</sup> 2006 Cross License, Section 7.5.

explain the meaning of the Agreement. *See Pacific Gas & Elec. Co. v. G.W. Thomas Drayage & Rigging Co., Inc.*, 69 Cal. 2d 33, 37 (1968) (“The test of admissibility of extrinsic evidence to explain the meaning of a written instrument is not whether it appears to the court to be plain and unambiguous on its face, but whether the offered evidence is relevant to prove a meaning to which the language of the instrument is reasonably susceptible.”); *Dore v. Arnold Worldwide, Inc.*, 9 Cal. 4th 384, 393 (2006) (noting that phrase “at any time” was not patently ambiguous in the context of a letter stating when a new hire could be terminated, but noting that the letter when considered as a whole might be ambiguous and thus provisionally considering extrinsic evidence.); Cal. Civ. Code § 1647 (“A contract may be explained by reference to the circumstances under which it was made, and the matter to which it relates.”); Cal. Civ. Code § 1645 (“Technical words are to be interpreted as usually understood by persons in the profession or business to which they relate, unless clearly used in a different sense.”).

**I. FORENSIC RESEARCH, EDUCATION, AND TRAINING ARE WITHIN THE SCOPE OF THE 2006 CROSS LICENSE BECAUSE THEY ARE USED IN, AND DONE IN PREPARATION FOR, LEGAL PROCEEDINGS**

**A. Forensic Research Is A Necessary Predicate to STR Analysis “For Use in, or Preparation for, Legal Proceedings.”**

Before any DNA profile can be admitted in legal proceedings, the DNA analysis kit that is used to generate that profile must undergo rigorous validation and its predictive capability must be studied across various populations. As noted by one court, “DNA testing requires a two-step process, one biochemical and the other statistical. The first step uses principles of molecular biology and chemistry to determine that two DNA samples look alike. The second step uses statistics to estimate the frequency of the profile in the population. Both steps must satisfy the Frye test.” *Brim v. State*, 695 So. 2d 268 (Fla. 1997). Forensic research is the only means by which a kit and the results of the analysis using the kit can fulfill this two-step requirement.

Addressing the second step first, populations have differing frequencies of genetic variation, meaning that the numerical probability that a sample belongs to an accused (or in the case of paternity, that the child is the offspring of the putative father) depends on the accused's subpopulation (Caucasian, Japanese, African American, etc.). Thus, prior statistical analysis of the performance of STR kits across different population groups is essential for DNA evidence to be admitted in legal proceedings. These forensic research analyses are referred to as population studies and provide the statistical underpinning for forensic scientists to testify in court about the probability of a DNA profile match. Declaration of Arthur Eisenberg in Support of Life's Supplemental Briefing Regarding Forensic Research, Education, and Training ("Eisenberg Decl."), at ¶ 5. DNA analysis kit manufacturers specify the probability of a kit providing a match for only handful of populations.<sup>2</sup> These probabilities are generated by determining the DNA profiles for a large number of samples and statistically analyzing the results. Many researchers have developed, and continue to develop, additional databases for a diversity of populations to provide greater statistical specificity during legal proceedings. For example, population studies have been performed on Inupiat and Yup'ik Eskimos and used in legal proceedings in Alaska. *E.g., Dayton v. Alaska*, 54 P.3d 817 (Ala. Ct. App. 2002). Such forensic research is common. A listing of 219 publications detailing population studies can be found at the National Institute of Science and Technology's web site. This list includes population

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<sup>2</sup> See Life Technologies website where the probability of identification of various kits is given for given for African American, US Caucasian, US Hispanic, and Native American populations. (<http://www.invitrogen.com/site/us/en/home/Products-and-Services/Applications/Human-Identification/AmpFISTR-Kit.html>) See also, Promega's website where the probability of identification of various Promega kits is given for African-American, Caucasian-American, Hispanic-American, and Asian-American populations. (<http://www.promega.com/products/pm/genetic-identity/population-statistics/power-of-discrimination/>). These probabilities are based on the results of population studies using STR kits.

studies for Bahamians, Jamaicans, Trinidadians, individuals of the Iberian Peninsula and Northern Africa, Turks, Andalusians, Brazilians, Scottish, Chinese, Vietnamese, and Bangladeshis.<sup>3</sup> The National DNA Advisory Board has codified the need for population study research in section 8 of its “Quality Assurance Standards for DNA Testing Laboratories” (“QAS”). (Exhibit 1 to Eisenberg Decl.)

In addition, to population studies, the QAS defines two areas where forensic research is required: “developmental validation” and “internal validation.” “Developmental validation is the acquisition of test data and the determination of conditions and limitations of a new or novel DNA methodology.” (See QAS § 2, “Definitions”) “Internal validation is the accumulation of test data within a laboratory to demonstrate that established methods and procedures perform as expected in the laboratory. *Id.* These research areas are required to qualify the DNA methods and results for use in legal proceedings.

“Forensic research . . . [is] necessary in order to qualify, accredit, and validate the scientific methodologies, forensic scientists, DNA laboratories, and STR kits used in forensic DNA analysis. Without these activities, testimony based on forensic casework using the STR kits would not be possible.” Eisenberg Decl., Ex 1, ¶ 8. “Forensic research and development is also essential for the first step of providing a DNA profile match. Without research in areas such as DNA collection, DNA extraction, quantifying the amount of DNA present, and understanding limitations of manual and automated procedures, a rigorous basis for explaining a DNA profile match and any anomalies could not be admitted in a court of law. These studies are necessary foundations for testimony in legal proceedings because they establish the reliability, reproducibility, accuracy, and acceptability of a particular methodology as evidence.” *Id.*, ¶ 6.

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<sup>3</sup> <http://www.cstl.nist.gov/strbase/populationdata.htm>

Development and validation of sample collection techniques and procedures require the use of STR kits. (See QAS § 8.5.) Such studies are essential for determining whether an adequate DNA profile can be achieved and whether the forensic community will accept it for DNA databasing or casework. Eisenberg Decl., Ex 1, ¶ 3. Optimization of automated extraction procedures also requires use of STR kits to allow the researcher to evaluate whether a given technique is suitable for high-throughput analysis. Eisenberg Decl., Ex 1, ¶ 9.

Thus, prior to acceptance as producing a robust, reproducible DNA profile, a DNA analysis kit must undergo rigorous examination by the forensic community. The research leading to commercialization of a kit is an absolute requirement for later use in legal proceedings. Without this developmental validation, a kit manufacturer could neither enhance existing kits, nor develop new kits, nor have the results of its kits used in legal proceedings. In sum, without the research performed by members of the forensics community, the STR kits would not be usable for their primary forensics role in legal proceedings and there would be no forensics “market” for them and no opportunity or ability for Life to sell STR kits in the forensics field.

B. Absent Forensic Education, There Would Be No Forensic Testing or Testimony in Legal Proceedings.

Forensic testing (casework) is complex and technical work, and as such would not be possible without the proper education in forensic science. Eisenberg Decl., ¶ 11. Accordingly, a forensic education is necessary as preparation for performing the actual forensic testing that will be used in legal proceedings. *Id.*

The Forensic Science Education Programs Accreditation Commission (FEPAC) of the American Academy of Forensic Sciences (AAFS) works to "develop, to implement, to maintain, and to enhance rigorous, consensus educational standards for undergraduate and graduate forensic science programs at accredited institutions of higher education." Eisenberg Decl., ¶ 12

(quoting FEPAC Accreditation Standards, ¶ 1.2). Toward this end, FEPAC has established Accreditation Standards for university programs leading to a degree in forensic science. *Id.* According to FEPAC, degree programs in forensic science "*shall* be . . . consistent with the goals and objectives of the forensic science community to *produce a technically skilled and educated workforce.*" *Id.* (quoting FEPAC Accreditation Standards, ¶ 4.1) (emphasis added). "[L]aboratory-based instruction" is also mandated by FEPAC. Eisenberg Decl., ¶ 13 (citing FEPAC Accreditation Standards, ¶ 4.3.1). The laboratory-based instruction includes actual use of STR kits by students and instructors. *Id.* The STR kits are used in the manner and for the purpose for which they were designed, *i.e.*, to analyze biological specimens for the identification of individuals by means of their genetic profiles. *Id.* Without forensic education, there would be no forensic testing for use in legal proceedings because no one would be qualified to perform such testing. *Id.* Forensics education is required preparation to qualify a forensic scientist to perform forensic testing and provide testimony in legal proceedings. *Id.*

The University of North Texas Health Sciences Center has a forensic education and training program accredited by the FEPAC of the AAFS. Eisenberg Decl., ¶ 14. It is a masters-level program, and its sole purpose and mission is to educate and train individuals to become forensic analysts who perform actual forensic casework. *Id.* The program is focused on forensic genetics, and DNA testing using STR kits involving human samples constitutes a substantial part of the curriculum. *Id.* Students in the program work on mock cases. *Id.* The only way that this can be done is to use the STR kits and techniques used in actual forensic testing. *Id.* Such use is therefore "in preparation for" actual forensic testing for use in legal proceedings. Moreover, such use also consists entirely of analyzing biological specimens for the identification of



individuals and therefore is also within the meaning of "Human Identity Applications" under the 2006 Cross License.

The University of Central Florida also has a forensics training program. Promega's own expert, John Ballantyne, is a professor at the University of Central Florida and explained in his deposition how their forensic science degree program produces qualified forensic scientists to perform forensic testing for use in legal proceedings:

Q: So the bachelor's and master's program are intended to train students, once they graduate, go out and get a career in the forensic field?

A: **Yes.** They're -- they're primarily -- our primary student body, they would -- most of them would be interested in a career in forensic science, most of them. But, of course, some of them go on to graduate school, medical school, teaching and other things. But *the vast majority coming into the programs wish to become forensic scientists. So we are trying to produce, you know, educated students for the forensic science community.*

Johnson Decl., Ex. 5 at 14:8-20 (emphasis added). Moreover, Professor Ballantyne explained how practical, hands-on training using STR kits is a necessary component of the curriculum:

Q: Do you know if, as part of either the bachelor's program or the master's program, there's any teaching using actual STR kits?

A: Yes, there is.

Q: For example, are they used in demonstrations?

A: Yeah. So, for example, in the undergraduate teaching -- undergraduate program, we have a course -- several courses involving forensic genetics, in which the students learn and perform DNA testing in the lab itself, yes.

Q: There's a lab component?

A: There is a lab component where *the students will, in fact, perform DNA testing.*

*Id.* at 14:21-15:9 (emphasis added).

The forensic training described by Professor Ballantyne, and specifically, the hands-on DNA testing using STR kits, reflects the mandatory educational standards set forth in the FEPAC Accreditation Standards discussed above. Again, under those Standards, academic forensic science programs are to be geared toward "produc[ing] a technically skilled and educated workforce." Eisenberg Decl., ¶ 12 (quoting FEPAC Accreditation Standards, ¶ 4.1). Thus, the forensic science program at the University of Central Florida is practically oriented and directly prepares graduates to perform forensic testing for use in actual legal proceedings. Moreover, students in the forensic training program are using the kits in the precise way they were designed and validated, *i.e.*, to analyze biological specimens for the identification of individuals. Thus, such uses also fall within the definition of "Human Identity Applications" in the 2006 Cross License

C. Absent Forensic Training, There Would Be No Forensic Testing or Testimony in Legal Proceedings

Upon completion of a forensic science education from an accredited degree program, graduates must undergo still further training and testing before they can perform actual forensic testing for use in legal proceedings. Eisenberg Decl., ¶ 15. This training is an essential prerequisite for a forensic scientist to testify about DNA profiles from STR kits in legal proceedings and, as such, constitutes "preparation for" legal proceedings. To testify in court, a forensic scientist not only be educated scientifically, but must also must be qualified by training and experience. Such training requires the demonstrated ability to use the STR kits to identify the individual who is the source of the DNA being analyzed. Due to the rigorous requirements for qualification and admission of DNA testimony, the forensic community has standardized the teaching and training of forensic scientists in the methods of gathering, preserving and analyzing

DNA samples. This is reflected in the Federal Bureau of Investigation's set of mandatory standards known as QAS. Eisenberg Decl., ¶ 16.

The QAS "describe the quality assurance requirements that laboratories performing forensic DNA testing or utilizing the Combined DNA Index System (CODIS) shall follow to ensure the quality and integrity of the data generated by the laboratory." Eisenberg Decl., ¶ 16 (quoting QAS ¶ 1). Under the QAS, forensic analysts who perform forensic testing for use in legal proceedings must first be trained according to stringent qualification standards. These include initial training requirements for casework analysis, competency testing, and ongoing proficiency testing, as specified in the QAS definition of an "Analyst":

an employee that has successfully completed the laboratory's *training requirements for casework sample analysis*, passed a *competency test*, and has entered into a *proficiency testing program* according to these standards. This individual conducts and/or directs the analysis of forensic samples, interprets data, and reaches conclusions.

Eisenberg Decl., ¶ 17 (quoting QAS ¶ 2) (emphasis added). Both competency testing and proficiency testing require the use of STR kits. *Id.* Under the QAS, an analyst who does not meet these training requirements cannot perform forensic testing for use in legal proceedings. *Id.* Forensic training is therefore integral to and a prerequisite for the use of forensic testing in legal proceedings. *Id.*

The QAS elaborates specifically on the standards for training of forensic analysts and technicians. Eisenberg Decl., ¶ 18. Again, these standards are mandatory. *Id.* (quoting QAS ¶ 5.1) ("Laboratory personnel *shall* have the education, training and experience commensurate with the examination and testimony provided.") (emphasis added). Specifically, they mandate hands-on experience with the tools and techniques used in actual forensic testing for use in legal proceedings, including hands-on use of STR kits. *Id.* For example, the QAS specify:

- "**Practical exercises** shall include the examination of a range of samples routinely encountered in casework." Eisenberg Decl., ¶ 18 (quoting QAS ¶ 5.1.2.1) (emphasis added).
- "The analyst shall complete the analysis of a range of samples routinely encountered in forensic casework prior to independent work using DNA technology." *Id.* (quoting QAS ¶ 5.4.2.1).
- "**Minimum** experience requirements: The analyst shall have six (6) months of forensic human DNA **laboratory experience**." *Id.* (quoting QAS ¶ 5.4.2) (emphasis added).
- "The training program shall teach and assess the **technical skills** and knowledge required to perform DNA analysis." *Id.* (quoting QAS ¶ 5.1.2.2) (emphasis added).
- "The training program shall require an individual's demonstration of competency." *Id.* (quoting QAS ¶ 5.1.2.2.1).
- "All analyst/technician(s), regardless of previous experience, shall successfully complete a competency test(s) covering the routine DNA methodologies to be used prior to participating in independent casework analysis." *Id.* (quoting QAS ¶ 5.1.2.2.3).
- Competency testing is required to prove that a forensic analyst or technician "has demonstrated **achievement of technical skills** and met minimum standards of knowledge **necessary to perform forensic DNA analysis**." *Id.* (quoting QAS ¶ 2) (emphasis added).

In sum, forensic analysts and technicians could not perform forensic testing for use in legal proceedings without first completing rigorous forensic training to acquire the requisite knowledge, technical skills, and hands-on experience. Eisenberg Decl., ¶ 19. In this way, forensic training on STR kits is both "for use in" and "in preparation for" legal proceedings, and is thus within the meaning of "Forensics and Human Identity Applications" under the 2006 Cross License.

Since the 2006 Cross License is governed by California law, it is noteworthy that any other interpretation would effectively render field of use devoid of meaning and would be untenable. *See, e.g., Wolf, et. al. v. Walt Disney Pictures and Television, et. al.*, 162 Cal. App. 4th 1107, 1136, 76 Cal. Rptr. 3d 585, 609-10 (Cal. App. 2d Dist., Div. 7, 2008) ("contract to be

interpreted consistent with contractual language and to avoid absurdity” thus, term “purchaser” did not include subsidiaries because to do so would lead to a meaningless result); *see also* Cal. Civil Code §§ 1638 (“The language of a contract is to govern its interpretation, if the language is clear and explicit, **and does not involve an absurdity**); 1643 (“A contract must receive such an interpretation as will make it lawful, **operative**, definite, **reasonable**, and capable of being carried into effect, if it can be done without violating the intention of the parties). “[U]nder California contract law, any conditions that make a contract reasonable, conform it to industry usage, or are necessary to carry it into effect, are deemed implied unless the contract manifests a contrary intention.” *Powertech Tech. Inc. v. Tessera, Inc.*, 660 F.3d 1301 (Fed. Cir. 2011) (citing Cal. Civ. Code § 1655-56; *Stockton Dry Goods Co. v. Girsh*, 36 Cal. 2d 677, 227 P.2d 1, 3-4 (Cal. 1951)).

If forensic research, education, and training were not included in the cross license, “within a finite period of time (a matter of months) there would be no market for [Life’s] STR kits. New lots of kits could not be validated. Existing forensic scientists could not take the required semi-annual proficiency tests using [Life’s] STR kits, which would disqualify them under the QAS from performing actual forensic casework [using Life kits]. New and improved kits and procedures could not be developed, tested, and validated [by Life]. Thus, to the extent problems arise with any existing kits, those problems could not be evaluated, tested, and refined. Such problematic kits would open the door to defense challenges at trial, casting doubt on the use and reliability of DNA testing overall.” Eisenberg Decl., ¶ 20. The interpretation urged by Promega would effectively deny Life the benefit of its bargain struck in the 2006 Cross License.

**II. PROMEGA HAS WAIVED THE RIGHT TO FURTHER RESTRICT THE SCOPE OF THE 2006 CROSS LICENSE TO EXCLUDE FORENSIC RESEARCH, EDUCATION, AND TRAINING**

Throughout discovery and during summary judgment briefing, Promega never once claimed that use of STR kits for forensic research, education, and training were outside the scope of the 2006 Cross License. It first did so after the Court's summary judgment ruling and immediately prior to the close of discovery on December 15, 2011. Promega has therefore waived its right to now assert that forensic research, education, and training are uses outside the scope of the 2006 Cross License. With the exception of the inducement and contributory infringement claims, the Court has ruled on infringement of the kit claims and the scope of the license. Promega should not be permitted to re-litigate those issues.

**CONCLUSION**

The foregoing discussion illustrates that forensic research, education, and training are inextricably linked to forensic casework and testimony. Without the forensics research, education, and training that Promega now seeks to label "non-forensic," the data which is integrally to the use of STR kits to generate DNA profiles admissible in court would not exist, and there would be no forensic scientists capable of generating those profiles. Life cannot have rights to forensic testing for use in legal proceedings without also having rights to forensic research and training that are required to validate the kits and teach forensic scientists how to use them. Any other interpretation would effectively render the licensed field devoid of meaning.

DATED: February 5, 2012.

By: /s/ Kristine E. Johnson

Francis M. Wikstrom (admitted *pro hac vice*)  
Kristine Edde Johnson (admitted *pro hac vice*)  
Michael R. McCarthy (admitted *pro hac vice*)  
Parsons Behle & Latimer  
201 South Main Street, Suite 1800

Salt Lake City, UT 84111  
Ph: 801-532-1234  
F: 801-536-6111  
fwikstrom@parsonsbehle.com  
kjohnson@parsonsbehle.com  
mmccarthy@parsonsbehle.com

Michael J. Modl  
Steven M. Streck  
Andrew J. Clarkowski  
Axley Brynelson, LLP  
2 E. Mifflin Street, Suite 200  
Madison, WI 53703  
Ph: 608-283-6705  
F: 608-257-5444  
mmodl@axley.com  
sstreck@axley.com  
aclarkowski@axley.com

Amy Sun (admitted *pro hac vice*)  
Life Technologies Corporation  
5791 Van Allen Way  
Carlsbad, CA 92008  
Ph: (760) 603-7200  
F: (760) 476-6048  
amy.sun@lifetech.com

Attorneys for Defendants